

**§ 524.1662**

**21 CFR Ch. I (4–1–02 Edition)**

**§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.**

**§ 524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.**

(a) *Specifications.* Each 3-ounce unit of oxytetracycline hydrochloride and hydrocortisone spray contains 300 milligrams of oxytetracycline hydrochloride and 100 milligrams of hydrocortisone with an inert freon propellant such that a 1-second spray treatment will deliver approximately 2.5 milligrams of oxytetracycline hydrochloride and 0.8 milligram of hydrocortisone.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions. The indications include prevention of bacterial infections in superficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus in dogs and cats.

(2) A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds. Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon after the initial favorable response has been obtained.

(3) Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

**§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.**

(a) *Specifications.* Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pink-eye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

(2) It is administered topically to the eye two to four times daily.

(3) Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

**§ 524.1742 N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid.**

(a) *Specifications.* The emulsifiable liquid contains 11.6 percent N-(mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Methods of application.* Methods of application to control the following conditions on beef cattle:

To control/method of use	Dilution rate (gal. drug: gal. of water)
Grubs:	
Dip .....	1:60
Pour-on .....	1:2
Spray .....	1:49